510(k) Summary *continue*

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	Biopsy guides in this submission	**K043425**
Intended Use	Needle Guide for BK Medical transducer 88xx*) *Needle guide 88XX*) provides guidance for needles or other interventional devices during an ultrasound-guided procedure. It positions the needle relative to the transducer, so that the needle image is in a specified position in the ultrasound image during procedures that require precise needle placement or biopsy.*	The Needle Guide provides guidance for a needle, catheter, biopsy apparatus or other interventional device by positioning it relative to the ultrasound transducer and the resulting image during a diagnostic ultrasound procedure in order to perform biopsy or precise needle placement.
Indications for use	Needle guide 88XX*) provides guidance for needles or other interventional devices during an ultrasound-guided procedure. It positions the needle relative to the transducer, so that the needle image is in a specified position in the ultrasound image during procedures that require precise needle placement or biopsy.	The Needle Guide provides guidance for a needle, catheter, biopsy apparatus or other interventional device by positioning it relative to the ultrasound transducer and the resulting image during a diagnostic ultrasound procedure in order to perform biopsy or precise needle placement.
Needle Guide angle	Fixed and Various	Various
Pre-sterilized	Yes	Yes
Removable options for Ultrasonic probe	Yes	Yes
For use with variety of Needles	Yes	Yes
Materials	MABS (incl. $BaSO_4$) MABS (incl. $BaSO_4$) and stainless steel	Nylon and ABS
Single Use / Disposable	Yes	Yes
Device description	The Needle Guide system consists of 3-4 primary components (depending on the intended transducer) which are used to provide alignment with an ultrasound transducer, in order to guide a needle in relation to the ultrasound image.	The Needle Guide system consists of 4 primary components which are used to provide alignment with an ultrasound transducer, in order to guide a needle in relation to the ultrasound image.

*)*8814; 8815; 8824*

Conclusion: The needle guides in this application have same intended use and the same characteristics as the predicate device.

B-K Medical therefore believes that the devices in this submission are substantially equivalent to the device in K043425.

K083667
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510(k) Summary

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical
Address: Mileparken 34, DK2730 Herlev, Denmark
Phone: +45 44528100
Fax: +45 44528199
Establishment registration number: 9680269

Contact person: Lars Oksby Hansen
Date prepared: 08 December 2008

Trade name: Needle Guide for 8814 (UA1335), for 8815 (UA1336), for 8824 (UA8824).

Common name: Needle Guide

Classification:
Diagnostic Ultrasound Transducer ITX (21 CFR 892.1570) Class II

Identification of predicate, legally marketed device:
Sheathes Needle Guide System (K043425)

Device description:
The BK Medical Needle Guides described are designed to be used with BK Medical' Ultrasound system to provide alignment with an ultrasound intra-operative transducer, in order to guide a needle (biopsy device, or other interventional device) in relation to the ultrasound image. The components for the Needle Guides are all single use disposable, and delivered sterile.
Note! The needle guides are delivered without needles.

Intended use.

Purpose:	Needle Guide for BK Medical transducer 88xx*) *Needle guide 88XX*) provides guidance for needles or other interventional devices during an ultrasound-guided procedure. It positions the needle relative to the transducer, so that the needle image is in a specified position in the ultrasound image during procedures that require precise needle placement or biopsy.*
Intended environment:	The device is for use by medical professionals in a physician office or hospital environment.

*)*8814; 8815; 8824*

Technological characteristics compared to the predicate device.
The predicate device has the same major technological characteristics as the subject device, see comparison below.

- Comparison with Sheathes Needle Guide System (K043425)

Continue on next page

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

Mr. Lars Oksby Hansen
Regulatory Manager
B-K Medical APS
Mileparken 34, DK-2730, Herlev
DENMARK

Re: K083667
Trade/Device Name: Needle guide for 8814 (UA1335), Needle guide for 8815 (UA1336), and Needle guide for 8824 (UA1337)
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: ITX
Dated: December 8, 2008
Received: December 11, 2008

Dear Mr. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k **083667**

Device Name: Needle guide for 8814 (UA1335), Needle guide for 8815 (UA1336), Needle guide for 8824 (UA1337).

Indications For Use:

Needle guide(s) provides guidance for needles or other interventional devices during an ultrasound-guided procedure. It positions the needle relative to the transducer, so that the needle image is in a specified position in the ultrasound image during procedures that require precise needle placement or biopsy.

Prescription Use _X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083667